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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HOWARD, ZACHARY C

ART UNIT PAPER NUMBER

1646

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/036,568

Applicant(s)

WILLSON ET AL.

Examiner

ZACHARY C. HOWARD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37, 42, 43, 47, 52 and 54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 37, 42, 43 and 47 is/are allowed.
- 6) ☒ Claim(s) 52 and 54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 December 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/051,843.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-646)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application, Amendments and/or Claims

The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Zachary C. Howard, Art Unit 1646, Technology 1600.

The amendment after final filed on 9/11/09 has been entered in full. Claims 53 and 55 are canceled (claims 1-36, 38-41, 44-46 and 48-51 were canceled previously).

Claims 37, 42, 43, 47, 52 and 54 are pending in the instant application.

In view of the new grounds of rejection (set forth below), the finality of the 3/19/09 Office Action is withdrawn.

Withdrawn Objections and/or Rejections

The rejection of claims 53 and 55 set forth in the previous Office Action (mailed 3/19/09) is moot in view of Applicants' cancellation of these claims.

New rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 52 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Vita et al, February 1995. Journal of Biological Chemistry, 270(8): 3512-3517 (reference AL on the 11/7/01 IDS).

Claim 52 recites "[a]n isolated polypeptide comprising amino acids 28-426 of SEQ ID NO: 4 or comprising an amino acid sequence having at least 95% identity with amino acids 28-426 of SEQ ID NO: 4, wherein said polypeptide bind IL-13".

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Vita et al teach that the "molecular nature of the IL-4/IL-13 receptors was also investigated by cross-linking studies using both ligands, ^{125}I -labelled IL-4 and ^{125}I -labelled $[\text{Phe}^{43}]$ IL-13-GYGY, on COS-43 and A431 cells" (pg 3514). Vita et al further teach that the "results are shown in Fig. 4" and "when the ^{125}I -labelled $[\text{Phe}^{43}]$ IL-13-GYGY was cross-linked ... one [band] ($\sim 70\text{kDa}$) on A431 cells were consistently detected" (pg 3514). The A431 cell line is a human epidermoid carcinoma cell line (pg 3512). The relevant art shows that this cell line inherently expresses a single form of the IL-13 receptor (see Murata et al, 1997. Biochemical and Biophysical Research Communications. 238: 90-94; cited here solely to provide evidence of inherency). Murata et al teach, "In epidermoid ... cell lines, only IL-13R α' was expressed" (see Abstract). Murata et al further teach that said epidermoid cell line is A431 (pg 91). Murata et al further teach that "Aman et al (18) have cloned another type of IL-13 R from HTLV-1 infected MT-2 cell line, using the sequence of the murine IL-13R cDNA (termed here, IL-13R α')" (pg 90). The sequence of the IL-13 receptor taught by Aman et al is 99.5% identical to instant SEQ ID NO: 4, and comprises a sequence that is 100% identical to residues 28-426 of SEQ ID NO: 4 (pg 29266 of Aman et al, 1996. Journal of Biological Chemistry. 271(46): 29265-29270; cited here solely to provide evidence of inherency). The sequence similarity is shown in the following alignment, where "Qy" is instant SEQ ID NO: 4 and "Db" is the sequence taught by Aman et al:

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Query Match          99.5%;  Score 2309.5;  DB 1;  Length 427;
Best Local Similarity 99.8%;
Matches 426;  Conservative 0;  Mismatches 0;  Indels 1;  Gaps 1;

Qy      1  HEWPARLCGLWALLLCAGGGGGGGG-APTETOPVTNLSVSVENLCTVIWTWNPFEGASS 59
      |||
Db      1  HEWPARLCGLWALLLCAGGGGGGGGAAPTETOPVTNLSVSVENLCTVIWTWNPFEGASS 60

Qy     60  NCSLWTFSHFGQKQDKKIAPETRSIEVPLMERICLQVGSQCSINSEKFPSSILVEKCISP 119
      |||
Db     61  NCSLWTFSHFGQKQDKKIAPETRSIEVPLMERICLQVGSQCSINSEKFPSSILVEKCISP 120

Qy    120  PEGDPESAVTELQCIWHNLSYHKSCWLPGRHTSPDTHYTLTYWHRSLERKHQCEHIFREG 179
      |||
Db    121  PEGDPESAVTELQCIWHNLSYHKSCWLPGRHTSPDTHYTLTYWHRSLERKHQCEHIFREG 180

Qy    180  QYFGCSFDLTKVDDSSFEQHSVQIVNKDNAGKIKFPSNIVPLTSRVKPDPPHIKNSLFHN 239
      |||
Db    181  QYFGCSFDLTKVDDSSFEQHSVQIVNKDNAGKIKFPSNIVPLTSRVKPDPPHIKNSLFHN 240

Qy    240  DDLTYVQWENPQMFISRCFLYVEVYVNSQTEHNVFTVQEAACENPEFERNVENTSFCRVP 299
      |||
Db    241  DDLTYVQWENPQMFISRCFLYVEVYVNSQTEHNVFTVQEAACENPEFERNVENTSFCRVP 300

Qy    300  GVLPTDLNTVIRIVKTNKLCYEDDKLWSNWSQENSIGKKRNSLTLYITELLIVPVIVAGAI 359
      |||
Db    301  GVLPTDLNTVIRIVKTNKLCYEDDKLWSNWSQENSIGKKRNSLTLYITELLIVPVIVAGAI 360

Qy    360  IVLLLLYLKRLKIIFFPIPDPGKIFKENFGQNDLTHWKKYDIYEKQTEETSUVVLE 419
      |||
Db    361  IVLLLLYLKRLKIIFFPIPDPGKIFKENFGQNDLTHWKKYDIYEKQTEETSUVVLE 420

Qy     420  NLKKASQ 426
      |||
Db     421  NLKKASQ 427

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Thus, A431 cells express a polypeptide comprising amino acids 28-426 of SEQ ID NO: 4, wherein said fragment binds IL-13. Furthermore, this polypeptide is found in isolated form in the cross-linked complex comprising labeled IL-13 and the IL-13R from A431 cells taught by Vita et al. Therefore, the teachings of Vita et al anticipate claim 52.

Claim 54 depends from claim 52 and is directed to a composition comprising the isolated polypeptide of claim 52. Vita et al teaches that the cross-linked IL-13 and IL-13R proteins were obtained by solubilized and subjected to electrophoresis (pg 3516). Therefore, Vita et al teaches a composition comprising the isolated polypeptide described above, and thus anticipates claim 54.

Note

Independent claim 37 requires an "isolated polypeptide comprising SEQ ID NO: 4". As noted above, the IL-13R polypeptide of Vita et al differs by one amino acid from instant SEQ ID NO: 4. Therefore, the isolated polypeptide of Vita et al does not comprise SEQ ID NO: 4 and therefore does not anticipate claim 37, or dependent

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claims 42, 43 and 47. No other prior art has been found that anticipates or renders obvious claims 37, 42, 43 or 47.

Conclusion

Claims 37, 42, 43, and 47 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Z. C. H./
Examiner, Art Unit 1646

/Bridget E. Bunner/
Primary Examiner, Art Unit 1647